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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/374,142	08/11/1999	HENRY C. LIN	P07-42146	3370

7590 12/04/2003
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EXAMINER

NAVARRO, ALBERT MARK

ART UNIT	PAPER NUMBER
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1645

DATE MAILED: 12/04/2003

23

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/374,142

Applicant(s)

LIN ET AL.

Examiner

Mark Navarro

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 12-14, 16-30 and 56-99 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 12-14, 16-30 and 56-99 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____ 6) ☐ Other: ____

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DETAILED ACTION

Applicant's amendment filed September 25, 2003 (Paper Number 22) has been received and entered.

Claim 15 has been canceled and new claims 80-99 have been added, consequently claims 12-14, 16-30 and 56-99 are pending in the instant application.

Claim Rejections - 35 USC § 112

1. The rejection of claims 12-14, 16-30, and 56-79 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for methods of treatment of bacterial overgrowth comprising detecting small intestinal bacterial overgrowth and at least partially eradicating the bacterial overgrowth, does not reasonably provide enablement for treatment of the diseases recited in the claims is maintained. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

Additionally this rejection is applied to newly added claims 80-99.

Applicants are asserting that the claim has been amended to delete the recitation of "an autoimmune disease selected from the group consisting of... systemic lupus erythematosus." Applicants conclude that the rejection has been overcome in light of this amendment.

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Applicants amendments and arguments have been fully considered but are not found to be persuasive.

In view of Applicants amendment the following references are applied:

McDonald et al (US Patent Application Publication 2003/0215421) sets forth that "Multiple sclerosis is an inflammatory disease of the central nervous system characterized by localized areas of demyelination. Although the etiology and pathogenesis of MS remain largely unknown, it is generally assumed that immune responses to myelin antigens contribute to the disease process." (See paragraph 384).

Repeating again, the instant application is enabled for methods of detecting bacterial overgrowth and partially eradicating the bacterial overgrowth. This however, does not fully enable methods of treating multiple sclerosis by partially eradicating the bacterial overgrowth. As set forth by McDonald et al, multiple sclerosis is a disease of the central nervous system. How does detecting and eradicating bacterial overgrowth in the duodenum, jejunum or ileum relate to a disease of the central nervous system? Furthermore, multiple sclerosis involves an immune response to myelin antigens, do any bacteria display myelin antigens? How does eradicating bacteria have any effect on autoimmune antibodies which react with myelin, (a protective sheath which surrounds bundles of nerves)? In a nutshell, even after eradicating the bacteria, the autoimmune antibodies which react with myelin antigens will remain and demyelination will continue to occur.

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Facts that should be considered in determining whether a specification is enabling, or if it would require an undue amount of experimentation to practice the invention include: (1) the quantity of experimentation necessary to practice the invention, (2) the amount of direction or guidance presented, (3) the presence or absence of working examples, (4) the nature of the invention, (5) the state of the prior art, (6) the relative skill of those in the art, (7) the predictability or unpredictability of the art, and (8) the breadth of the claims. See In re Wands, 858 F.2d 731,737, 8 USPQ2d 1400, 1403 (Fed. Cir. 1988). The Federal Circuit has noted, however, that only those factors that are relevant based on the facts need to be addressed. See Enzo Biochem. Inc. v. Calgene, Inc. 188 F.3d 1362, 1371, 52 USPQ2d 1129, 1135 (Fed. Cir. 1999).

In considering these factors, Applicants specification is absent any working examples which shows treatment of multiple sclerosis. Again, treatment of the bacterial overgrowth is not being question. However, have the pathogenic signs of demyelination been arrested or reversed? Since no working examples showing successful treatment of MS are present this consideration is found to be lacking. Furthermore, with respect to the nature of the invention, and state of the prior art. McDonald et al has set forth that the etiology of multiple sclerosis is unknown. Given that the etiology is unknown it is simply unpredictable to ascertain if eradicating bacteria will treat a disease of unknown etiology.

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Kong et al (US Patent Application 2003/0124566) set forth that Irritable Bowel Syndrome is of unknown etiology. (See paragraph 2).

Stoll (US Patent Application 2002/0018809) set forth that the etiology and pathophysiology of fibromyalgia are unknown, but it is clear that the central nervous system is involved. (See paragraph 2).

Roelens et al (US Patent Application 2003/0152919) set forth that the etiology of chronic fatigue syndrome is unknown and involves neurocognitive dysfunction. (See paragraph 9).

Cohen et al (US Patent Application 2003/0185754) set forth that there is a strong need to identify genes involved in disorders such as depression. (See paragraph 66).

Brunner et al (US Patent Application 2003/0050308) set forth that although the precise etiology of ADHD is unknown, neurotransmitter deficits, genetics, and perinatal complication have been implicated. (See paragraph 8).

Again referring back to the Wands analysis, each of these contemplated treatments involves diseases of unknown etiology and largely involving the central nervous system. Each of the cited references demonstrate the unpredictability of the invention, given that the cause of the disease is unknown. Simply eradicating a bacterial small intestine overgrowth offers no benefit to a disease of unknown origin affecting the central nervous system, especially considering that the blood brain barrier would prevent any bacterial agent from affecting the central nervous system in the first place.

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For reasons of record in Paper Number 20, as well as the reasons set forth above this rejection is maintained.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mark Navarro, whose telephone number is (703) 306-3225. The examiner can be reached on Monday - Thursday from 8:00 AM - 6:00 PM. The examiner can be reached on alternate Fridays. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Lynette Smith can be reached at (703) 308-3909.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist, whose telephone number is (703) 308-0196.

Papers related to this application may be submitted to Group 1645 by facsimile transmission. Papers should be faxed to Group 1645 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the official Gazette 1096 OG 30 (November 15, 1989). The CMI Fax Center number is (703) 308-4242.



Mark Navarro

Primary Examiner

November 25, 2003